JUN - 7 2001

K 011364

510(K) Summary for the Siemens Custom TCI

1.	**Applicant's Name & Address:**	Siemens Hearing Instruments 10 Constitution Ave. PO Box 1397 Piscataway, NJ 08855
2.	**Contact Person, Telephone and e-mail Address:**	Dave Slavin 732-562-6658 dslavin@siemens-hearing.com
3.	**Device Trade of Proprietary Name:**	Custom TCI (Tinnitus Control Instrument)
4.	**Device Common Name / Classification Name:**	**Tinnitus Masker**
	Product Code:	**KLW**
5.	**Establishment Registration Number:**	2217809
6.	**Address of Manufacturing Site:**	Siemens Hearing Instruments 10 Constitution Ave. PO Box 1397 Piscataway, NJ 08855
7.	**Classification of Device:**	Class II
8.	**Marketed Devices to which the claim of substantial equivalence is made:**	K974751 General Hearing Instruments Tranquil Tri-OE

9. Compliance with Section 514, Performance Standards: Not Applicable

10. Indications for Use:

The TCI is a custom in-the-ear style electronic, air conduction broad-band noise generator intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Custom TCI is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do not desire or need amplification. This product may also be used with children 5 years of age or older.

11. Description of Device:

Custom TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is available in a full in-the-ear, half shell, in-the-canal, or helix shell. It is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements.

12. Comparison Information to Predicate Device:

The Custom TCI is substantially equivalent to the General Hearing Instruments Tranquil Tri-OE (K974751). The Tranquil is also a noiser for tinnitus, with no amplification characteristics. The Siemens Custom TCI differs from the Tranquil, in that the Custom TCI is a digital product and is fully programmable, which increases the flexibility of the device.

The following table compares the Siemens Hearing Instruments Custom TCI device and General Hearing Instruments Tranquil Tri-OE.

	Siemens Hearing Instrument Custom TCI Device	General Hearing Instruments Tranquil Tri-OE
Intended Use	Mask tinnitus as part of tinnitus management	Mask tinnitus as part of tinnitus management

	program	program
Target Population	Adults and children (≥5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	 Digital Yes Four Yes	 Analog No One Yes
Physical Description	Custom product, available as helix, in-the-ear, half shell, and in-the-canal	Custom product, available as in-the-ear and mini-canal
RMS Output Characteristics White noise Pink noise Speech noise High-tone noise	 86 dB SPL 75 dB SPL 71 dB SPL 81 dB SPL	 75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

Custom TCI Comparison with Predicate Device

13. Information required under Title 21, Section 874.3400, and not already provided above.

Risks

The maximum output for Custom TCI is 86 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

Hearing Healthcare Professional Diagnosis:

The sale and fitting of the Siemens Custom TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:
Relief of tinnitus symptoms may be provided by this device when utilized with appropriate counseling and/or tinnitus therapy.

Warnings for Safe Use
As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

Siemens Hearing Instruments
c/o Dave Slavin
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855-1397

Re: K011364
Trade Name: Custom TCI
Regulation Number: 874.3400
Regulatory Class: II
Product Code: 77 KLW
Dated: May 14, 2001
Received: May 15, 2001

Dear Mr. Slavin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) NUMBER (IF KNOWN): **K011364**

DEVICE NAME: **CUSTOM TCI**

INDICATIONS FOR USE:

Tinnitus is a noise (buzzing, ringing, or roaring) perceived by an individual where there is no external acoustic stimulus (Mueller and Hall, 1998). The device is intended for use by people who experience tinnitus as a part of a tinnitus management program. Patients should receive medical evaluations to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management. Tinnitus management programs include a complete audiologic assessment, tinnitus evaluation, directive counseling, and extended use of a low-level noise generator to facilitate habituation of the tinnitus. While not specifically endorsed by Siemens Hearing Instruments, the TRT (Tinnitus Retraining Therapy) method is one example of a tinnitus management program (Jasterboff, 1993).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011364